

**REMARKS****Status of the claims**

Claims 1-60 are pending in the application. Claims 1-33 and 53-60 are withdrawn from consideration. Claims 34-52 stand rejected. Claim 34 is amended. No new matter is added.

**Amendment to the claim**

Claim 34 is amended to remove the phrase "of the applicator of" and remove any redundancies in the language as suggested by the Examiner. The claim has also been amended to replace the word "treating" with "ablating". This is supported by the claim as it is a method of ablating and the steps recited will inherently cause ablation.

**Priority**

The Examiner states that the disclosure of the prior-filed application, Application No. 10/670,618 and 60/413,351, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for claims 47 and 48. As such, these limitations will only be given priority to the filing date of the current application. The Applicants respectfully disagree.

While the prior-filed applications, Application No. 10/670,618 and 60/413,351, do not specifically mention the use of magnetic fields and eddy currents per se, it does disclose that electromagnetic energy may induce alterations of the stratum corneum [paragraph 0006] and the use of multiple electrodes to measure the

electrical properties of the treatment site (tissue) and provide feedback to the device [paragraph 0055]. Eddy currents are currents induced in conductor by a changing magnetic field. This current creates magnetic fields that oppose the change of the original magnetic field and cause repulsive or drag forces. Thus, the prior-filed Application No. 10/670,618 does provide support for the use of magnetic field and eddy currents because, in theory, eddy currents can be induced in the stratum corneum by electromagnetic energy. Thus, the Applicants respectfully request that claims 47 and 48 be given the priority of the prior-filed application.

The 35 U.S.C. §112 rejection

Claims 34-52 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. More particularly, the Examiner states that the first limitation of claim 34 appears to recite a device having an applicator while the second limitation appears to recite an applicator having a device. Furthermore, the Examiner states that claim 34 is fraught with unclear redundant language.

The Applicants have amended claim 34 to remove language which limits an applicator having a device. The Applicants have removed any redundancies in claim 34. In view of this amendment, the Applicants request that the rejection of claims 34-52 under 35 U.S.C. §112 be removed.

The 35 U.S.C. §102 rejection

Claims 34-46 and 49-52 are rejected under 35 U.S.C. §102(e) as being anticipated by **Miller et al.** (US 2003/0208235).

The Examiner states that **Miller et al.** disclose a method comprising the steps of contacting a tissue with an applicator actuated by a driving means- the application of an abrasive driven mechanically- which is performed in conjunction with the iontophoresis; dispensing a pharmaceutical while altering the tissue; monitoring electrical current between an active and return electrode; applying electrically conductive fluid interface between the electrode and the tissue; and controlling the device via a microprocessor in a controller.

The Applicants submit that **Miller et al.** disclose a device and method for iontophoretically transporting a compound through localized region of an individual's body tissue. More particularly the device comprises multiple iontophoretic electrodes, a current source and a monitoring means. **Miller et al.** also disclose means for monitoring and controlling electrical resistance at the site undergoing iontophoresis.

The Applicants submit that **Miller et al.** do not anticipate the claimed invention because they are drawn towards distinct methods. **Miller et al.** is directed towards a method of iontophoresis. Thus, their device and method alter the skin's permeability thereby increasing the migration of a particular ion through the skin. The advantage of their method is that the skin need not be ablated or punctured via a needle.

In contrast, the claimed invention is drawn to a method of ablating tissue which also increase the permeability of particular molecules across skin but results in

physically altering the stratum corneum. Therefore, the claimed invention is novel because it is drawn to a wholly different method than that disclosed in **Miller et al.**

The Examiner also points in responding to prior arguments that **Miller et al.** disclose a iontophoretic device which may be aided by a separate ablation technique. Paragraph 0087 of **Miller et al.** list techniques such as laser ablation. Clearly, **Miller et al.** cannot anticipate the claimed invention since the device disclosed in **Miller et al.** cannot ablate tissue as conceded by the Examiner. Moreover, the ablation described in **Miller et al.** is achieved by a wholly different method, such as laser ablation, than the method described in the claimed invention. In other words, the claimed invention is not anticipated since **Miller et al.** teach ablation by techniques such as laser ablation rather than the claimed method and as pointed out by the Examiner, the iontophoretic device of **Miller et al.** do not ablate tissue.

In view of the claim amendment, the Applicants respectfully request that the rejection of claims 34-46 and 49-52 under 35 U.S.C. §102 be removed.

Claims 34-42 and 47-52 are rejected under 35 U.S.C. §102(e) as being anticipated by **Handy et al.** (US 2003/0032995).

The Examiner states that **Handy et al.** disclose a method comprising the steps of contacting a tissue with an applicator actuated by a driving means; dispensing a pharmaceutical while altering the tissue; generating and monitoring eddy currents to control the device via microprocessor in a controller. Applicants respectfully disagree.

The Applicants submit that **Handy et al.** disclose a device or method of treating an individual by administering a magnetic composition comprising at least one

magnetic particle attached to a ligand specific to a predetermined target in the patient and applying an alternating magnetic field to the magnetic composition to inductively heat the composition. More particularly, the composition is administered via intraperitoneal injection, intravascular injection, intramuscular injection, subcutaneous injection, topical, inhalation, ingestion, rectal insertion, wash, lavage or rinse perisurgically, or extracorporeal administration into patient's bodily materials.

The Applicants respectfully submit that **Handy et al.** do not anticipate the claimed invention for the following reasons. As stated in the prior response, **Handy et al.** do not disclose a method of ablating as recited in the claimed invention. In the response to the prior argument, the Examiner cites paragraph 0012 of **Handy et al.** as evidence that the device and method of **Handy et al.** is drawn to a method of using magnetically induced thermotherapy (thermo-ablation) to destroy diseased cells. Paragraphs 0012, 0013 and 0014 of **Handy et al.** clearly state that this so-called "thermo-ablation" technique is radio-frequency induced "regional heating of deep-seated tumors." Since heat is inducing the cell death, any ablation which occurs is not the result of an applicator whose surface comes in contact with the tissue and is driven by an actuator.

In distinct contrast, claim 34 recites a method of ablation wherein the ablation is affected by contacting a surface of an applicator of a device to the area of interest and actuating the applicator, wherein the driving motion of the application causes the ablation to occur. Thus, it is clear that any ablation which may be described in **Handy et al.** is not the result of the recited steps of the claimed invention, but rather by applying heat directed to the area of interest. Furthermore, **Handy et al.** do not

disclose any other methods of ablation, more specifically, the method of ablation recited in the claimed invention.

The Applicants submit that the device disclosed in Handy et al. cannot inherently carry out the process recited in the claimed method because it does not teach an actuator which can drive a surface designed to contact the area of interest. Contrary to the Examiner's assertion, the solenoid described in Handy et al. is not an actuator which can drive the surface of an applicator in such a way as to ablate tissue. As discussed supra, any ablation which may be described in Handy et al. is heat induced ablation and not the result of the steps described in the claimed invention.

Therefore, the Applicants submit that Handy et al. do not anticipate the claimed invention because Handy et al. do not disclose a method of ablating tissue by the steps recited in the claimed invention. In view of the arguments presented herein, the Applicants respectfully request that the rejection of claims 34-42 and 47-52 under 35 U.S.C. §103 be removed.

#### Double Patenting

Claims 34-46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 12/321,885 and claims 1 and 34-37 of copending Application No. 10/670,618.

The Examiner states that although the conflicting claims are not identical, they are not patentably distinct from each other because each disclose methods of

treating tissue comprising the steps of contacting the tissue with an actuated applicator and monitoring an electrical property of the tissue during treatment.

Applicants include herewith a Terminal Disclaimer under 37 C.F.R. §1.321 Accordingly, Applicants respectfully request that the provisional double patenting rejection of claims 34-46 be withdrawn.

This is intended to be a complete response to the Office Action mailed July 14, 2009. A Petition for Extension of Time and PTO Form-2038 are also enclosed herewith. In absence of this form, please debit the petition fee or any other fees due from Deposit Account 07-1185. Applicants submit that the pending claims are in condition for allowance. If any issues remain outstanding, please telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

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